STATES OF

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/038,261	03/10/98	RIETER	R 30435.54USU1

EXAMINER

HM12/0525

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ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 05/25/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on March 10, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-43 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-43 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Sequence Compliance

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.8821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, there is no sequence data submitted. Please see 37 CFR 1.821 through 1.825 and MPEP 2422, particularly MPEP 2422.03-2422.07.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer from the date of this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821 (g). **Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).** In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 24, drawn to a PSCA protein and associated peptides, classified in class 530, subclass 350+.

II. Claims 17-23, drawn to a polynucleotide sequence, classified in class 536, subclass 23.1+.

III. Claim 7-16, 25-26, and 32, drawn to an antibody and method of detecting PSCA, classified in class 530, subclass 387.1+.

IV. Claims 27-31 and 33, drawn to a method of detecting a nucleic acid encoding PSCA in a tissue by DNA hybridization, classified in class 536, subclass 24.3.

V. Claims 34, 38, and 40-42, drawn to a method diagnosing the presence of cancer by quantifying the concentration of PSCA protein, classified, for example, in class 435, subclass 7.1+.

VI. Claim 35, 39, and 40-42, drawn to a method of diagnosing cancer by quantifying the level of nucleic acid encoding PSCA in a tissue, classified in class 435, subclass 6.

VII. Claim 36, drawn to a method monitoring the course of cancer in a subject by quantifying the concentration of PSCA protein in a patient at different time points, classified in class 435, subclass 7.23.

VIII. Claim 37, drawn to a method monitoring the course of cancer in a subject by quantifying the concentration of RNA encoding PSCA in a patient at different time points, classified in class 435, subclass 6.

IX. Claim 43, drawn to a method of selectively killing cells expressing PSCA, classified in class 424, subclass 138.1.

3. The inventions are distinct, each from the other because of the following reasons:

4. The proteins compositions of Group I is related to the nucleic acids of Group II since the polynucleotides encode the protein compositions. Although they are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from non-recombinant cells. Further, the DNA may be used for processes other than the production of the protein, such as a nucleic acid hybridization assay. The examination of both groups would require different searches in the U.S. Patent Shoes and the scientific literature, and would require the consideration of different patentability issues.

The proteins of Group I are related to the antibodies of Group III by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two compositions, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used for other materially different processes in its own right, such as in a method of treatment, or in assays for the identification of agonists or antagonists for the protein. The examination of both groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The nucleic acid of Group II and the antibody of Group III are different chemical compositions with different chemical properties and different methods of use. The examination

of both groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of groups (IV, VI, and VIII), (V and VII), and IX differ in the method objectives, method steps and parameters, in the regents used, and have different measurable endpoints and measurement criteria. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of groups IV, VI, and VIII differ in the method objectives, method steps and parameters, and have different measurable endpoints and measurement criteria. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of groups V and VII differ in the method objectives, method steps and parameters, and have different measurable endpoints and measurement criteria. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Inventions III and (V and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the antibodies Invention II can also be used in a therapeutic method directed to selectively killing cells expressing the PSCA.

Inventions III and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies Invention II can also be used to diagnose cancer in a patient.

Inventions II and (IV, VI, and VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides Invention II can also be used in methods of gene therapy.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Conclusion

8. Any inquiry concerning the communication or earlier communications from the examiner should be directed to Timothy A. Worrall, Ph.D. whose telephone number is (703) 308-9348. The examiner can normally be reached on Monday through Friday from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014.

Communications via Internet-e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements under 35 U.S.C.122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997, at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Timothy A. Worrall, Ph.D.
May 13, 1999

JULIE BURKE
PRIMARY EXAMINER